DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

PROCESSING IN STEAM IN CONTINUOUS AGITATING RETORTS

(Retort Survey)

INSTRUCTIONS

Complete the question blocks below. Draw a diagram of the retort or obtain one from the firm and attach it to the EIR as an exhibit. Report all pipe sizes as inside diameter (ID). Refer to 21 CFR Part 113.40(c) and pp 28-30 of LACF Guide Part 2.

If problems are found with the firm's retort equipment or processing system, refer the reader to the narrative Turbo EIR under "Objectionable Conditions and Management's Response," and include a narrative explanation of specific problems and evidence under the subheading "Supporting Evidence and Relevance." Submit the completed form as an EIR attachment.

RETORT DESCRIPTION

RETORT NO.	*CAN SIZE	COOKER CAPACITY	STEPS/REEL
	NO. OF PRECOOKERS	NO. OF PRESS COOLERS	NO. OF AMOS. COOLERS

*List the Can Size covered during the inspection.

COMPUTER CONTROLS

DOES A COMPUTER CONTROL ANY OF THE RETORT FUNCTIONS? ..... Yes ☐ No ☐

EXPLAIN:

DOES THE FIRM HAVE DOCUMENTATION ON HAND THAT INDICATES THAT THE COMPUTER SYSTEM HAS BEEN VALIDATED?

Yes ☐ No ☐

EXPLAIN:

IS RECORD KEEPING PART OF THE COMPUTER FUNCTION? ..... Yes ☐ No ☐

IF YES, DOES THE RECORD KEEPING COMPLY WITH 21 CFR PART 11? ..... Yes ☐ No ☐

INDICATING MERCURY IN-GLASS THERMOMETERS (113.40(c)(1))

IS THE RETORT EQUIPPED WITH AT LEAST ONE MERCURY IN-GLASS (MIG) THERMOMETER? ..... Yes ☐ No ☐

IS THE RETORT EQUIPPED WITH ANOTHER TYPE OF TEMPERATURE INDICATING DEVICE? ..... Yes ☐ No ☐

IF YES, DESCRIBE THE INDICATOR:

ARE SCALE DIVISIONS EASILY READABLE TO 1°F (.5°C)? ..... Yes ☐ No ☐

NO. OF DEGREES F OR C/IN. OF GRADUATED SCALE: _____. *(TEMP. RANGE MUST NOT EXCEED 17°F(8°C) PER INCH (4°C/CM) OF GRADUATED SCALE. SEE LACF GUIDE, P. 14.)*

DATE LAST TESTED FOR ACCURACY:

*(THERMOMETERS **SHALL** BE TESTED FOR ACCURACY AGAINST A KNOWN ACCURATE STANDARD THERMOMETER UPON INSTALLATION AND AT LEAST ONCE A YEAR THEREAFTER; RECORDS OF ACCURACY CHECKS THAT SPECIFY DATE, STANDARD USED, METHOD USED, AND PERSON PERFORMING THE TEST **SHOULD** BE MAINTAINED. EACH THERMOMETER **SHOULD** HAVE A TAG, SEAL, OR OTHER MEANS OF IDENTITY THAT INCLUDES THE DATE IT WAS LAST TESTED FOR ACCURACY.)*

STANDARD USED FOR THE TEST:

NAME AND TITLE OF PERSON WHO PERFORMED TEST:

IS THE LAST TEST DATE IDENTIFIED ON THE THERMOMETER? ..... Yes ☐ No ☐

WERE CALIBRATING TEST RECORDS PREPARED/MAINTAINED? ..... Yes ☐ No ☐

(SHOULD REQUIREMENT)

DESCRIBE THE FIRM'S ACTIONS REGARDING MIG THERMOMETERS THAT WERE OUT OF CALIBRATION:

IS THE MERCURY UNDIVIDED? ..... Yes ☐ No ☐

*(A THERMOMETER THAT HAS A DIVIDED MERCURY COLUMN OR THAT CANNOT BE ADJUSTED TO THE STANDARD **SHALL** BE REPAIRED OR REPLACED.)*

WHEN MIG THERMOMETERS ARE FOUND TO BE PROVIDING READINGS ABOVE THE ACTUAL TEMPERATURES, DOES THE FIRM EVALUATE PRODUCTS PRODUCED USING THOSE THERMOMETERS? ..... Yes ☐ No ☐

DESCRIBE THE FIRM'S PROCEDURES:

IS THE THERMOMETER LOCATED WHERE IT IS EASY TO READ ACCURATELY? ..... Yes ☐ No ☐

*(**SHALL** REQUIREMENT)*

THE SENSOR BULB IS LOCATED IN THE ..... Retort Shell ☐, or External Well ☐

*(**SHALL** REQUIREMENT)*

DIAMETER OF OPENING FROM RETORT TO EXTERNAL WELL: _____ BLEEDER SIZE: _____

*(OPENING **SHALL** BE AT LEAST 3/4-IN. DIA.)* *(BLEEDER **SHALL** BE AT LEAST 1/16-IN. DIA.)*

DOES THE BLEEDER EMIT STEAM CONTINUOUSLY DURING PROCESSING? ..... Yes ☐ No ☐

*(**SHALL** REQUIREMENT)* IF NO, EXPLAIN:

IF A MUFFLER IS USED ON BLEEDER(S), WHAT EVIDENCE DOES THE FIRM HAVE THAT IT DOES NOT RESTRICT FREE FLOW OF STEAM?

*(**SHALL** REQUIREMENT – 113.87(g))*

IS THE MERCURY THERMOMETER USED AS THE REFERENCED INSTRUMENT DURING PROCESSING? ..... Yes ☐ No ☐

*(**SHALL** REQUIREMENT)*

TEMERATURE RECORDING DEVICE (113.40(c)(2))

IS THE RETORT EQUIPPED WITH A TEMPERATURE RECORDING DEVICE? ..... Yes ☐ No ☐

TYPE OF TEMPERATURE RECORDER ..... Round Circular Chart ☐ Strip Chart ☐ Other ☐

IF OTHER, EXPLAIN:

DO THE CHART SPECIFICATIONS MEET THE REQUIREMENTS OF PART 113.40(c)(2)? ..... Yes ☐ No ☐

(GRADUATIONS ON THE TEMPERATURE-RECORDING DEVICE SHALL NOT EXCEED 2°F (1°C) WITHIN A RANGE OF 10°F (5.5°C) OF THE PROCESSING TEMPERATURE. EACH CHART SHALL HAVE A WORKING SCALE OF NOT MORE THAN 55°F/IN (12°C/CM) WITHIN A RANGE OF 20°F (10°C) OF THE PROCESSING TEMPERATURE – 113.40(b)(2). ALSO, SEE P. 14 OF LACF FIELD GUIDE - PART 2.)

IS THE TEMPERATURE CHART ADJUSTED TO AGREE AS NEARLY AS POSSIBLE WITH BUT NOT HIGHER THAN THE KNOWN ACCURATE MERCURY-IN-GLASS THERMOMETER DURING THE PROCESSING PERIOD? ..... Yes ☐ No ☐

(SHALL REQUIREMENT; NOTE ANY DIFFERENCE BETWEEN THE RECORDING THERMOMETER AND THE MERCURY-IN-GLASS THERMOMETER AND WHICH READING IS HIGHER.)

IS THERE A MEANS FOR PREVENTING UNAUTHORIZED ADJUSTMENTS? ..... Yes ☐ No ☐

*(A MEANS OF PREVENTING UNAUTHORIZED CHANGES IN ADJUSTMENTS **SHALL** BE PROVIDED; A LOCK OR NOTICE FROM MANAGEMENT STATING "ONLY AUTHORIZED PERSONS ARE PERMITTED TO MAKE ADJUSTMENTS" & POSTED AT OR NEAR THE RECORDING DEVICE IS A SATISFACTORY MEANS FOR PREVENTING UNAUTHORIZED CHANGES.)*

IS THE CHART DRIVE TIMING MECHANISM ACCURATE? ..... Yes ☐ No ☐

IF NO, EXPLAIN:

IS THE RECORDER COMBINED WITH A STEAM CONTROLLER? ..... Yes ☐ No ☐

THE TEMPERATURE SENSING BULB IS INSTALLED IN THE ..... Retort Shell ☐, or External Well ☐

*(THE TEMPERATURE-RECORDER BULB **SHALL** BE INSTALLED EITHER WITHIN THE RETORT SHELL OR IN A WELL ATTACHED TO THE SHELL.)*

DOES THE TEMPERATURE RECORDER BULB WELL HAVE A 1/16-IN. DIA. OR LARGER BLEEDER THAT EMITS STEAM CONTINUOUSLY DURING THE PROCESSING PERIOD? ..... Yes ☐ No ☐ N/A ☐

*(**SHALL** REQUIREMENT)*

IF A MUFFLER IS USED ON THE BLEEDER, DOES THE FIRM HAVE DOCUMENTED EVIDENCE THAT IT DOES NOT BLOCK THE FLOW OF STEAM? ..... Yes ☐ No ☐ N/A ☐

(SHALL REQUIREMENT – 113.87(g))

PRESSURE GAGE (113.40(c)(3))

IF A PRESSURE GAGE IS PRESENT ON THE RETORT COOKER SHELL, IS IT GRADUATED IN DIVISIONS OF 2 LBS. OR LESS?

Yes ☐ No ☐

*(**SHOULD** REQUIREMENT)*

IS THE PRESSURE COOLING SHELL EQUIPPED WITH A PRESSURE GAGE? ..... Yes ☐ No ☐

IF THE COOKER SHELL IS CONNECTED BY TRANSFER VALVES TO A PRESSURE COOLING SHELL, IS THE PRESSURE IN THE COOLER LESS THAN THE PRESSURE IN THE COOKER? ..... Yes ☐ No ☐

(THE PRESSURE IN THE PRESSURE COOLER SHOULD BE AT LEAST 2 PSIG LESS THAN THE PRESSURE IN THE COOKER TO PREVENT BACKFLOW OF COOLING WATER INTO THE COOKER.)

STEAM CONTROLLER (113.40(c)(4))

IS THE STEAM CONTROLLER AUTOMATIC? ..... Yes ☐ No ☐

*(EACH RETORT **SHALL** BE EQUIPPED WITH AN AUTOMATIC STEAM CONTROLLER TO MAINTAIN THE RETORT TEMPERATURE.)*

IS THE STEAM CONTROLLER TEMPERATURE OR PRESSURE ACTUATED? ..... Temp. ☐ Press. ☐

(THE STEAM CONTROLLER MAY BE ACTUATED BY A TEMPERATURE SENSOR POSITIONED NEAR THE MERCURY-IN-GLASS THERMOMETER; A STEAM CONTROLLER ACTIVATED BY THE STEAM PRESSURE OF THE RETORT IS ACCEPTABLE IF IT IS CAREFULLY MAINTAINED SO IT OPERATES SATISFACTORILY.)

REPORT THE **MANUFACTURER**, **MODEL**, **TYPE** AND **SIZE** OF THE AUTOMATIC STEAM CONTROL VALVE:

IF THE TEMPERATURE (STEAM) CONTROLLER IS AIR OPERATED, DOES THE SYSTEM HAVE AN ADEQUATE FILTER TO ASSURE A SUPPLY OF CLEAN, DRY AIR? ..... Yes ☐ No ☐

*(AIR OPERATED TEMPERATURE CONTROLLERS **SHOULD** HAVE ADEQUATE FILTER SYSTEMS TO ASSURE A SUPPLY OF CLEAN, DRY AIR 113.40(C)(2).)*

BLEEDERS (113.40(c)(5))

ARE BLEEDERS (EXCEPT THOSE FOR THERMOMETER WELLS) 1/8-INCH OR LARGER IN DIAMETER? ..... Yes ☐ No ☐

*(**SHALL** REQUIREMENT)*

ARE THESE BLEEDERS LOCATED ALONG THE TOP OF THE RETORT NO MORE THAN 8 FT. APART AND WITHIN APPROXIMATELY 1 FT. OF THE OUTERMOST LOCATION OF CONTAINERS AT EACH END? ..... Yes ☐ No ☐

*(**SHALL** REQUIREMENT)*

ARE THE BLEEDERS ARRANGED SO THE OPERATOR CAN OBSERVE THAT THEY ARE OPERATING PROPERLY?

Yes ☐ No ☐

*(**SHALL** REQUIREMENT)*

ARE THE BLEEDERS WIDE OPEN DURING THE ENTIRE PROCESS INCLUDING THE COME-UP TIME? ..... Yes ☐ No ☐

IF A MUFFLER IS USED ON BLEEDERS, DOES THE FIRM HAVE DOCUMENTED EVIDENCE THAT IT DOES NOT RESTRICT FREE FLOW OF STEAM? ..... Yes ☐ No ☐ N/A ☐

(SHALL REQUIREMENT – 113.87(G))

VENTING & CONDENSATE REMOVAL (113.40(c)(5&6))

IS THE RETORT VENTED TO REMOVE AIR PRIOR TO PROCESSING? ..... Yes ☐ No ☐

*(**SHALL** REQUIREMENT)*

NUMBER OF VENTS: _____ DIAMETER: _____ LENGTH: _____

LOCATION:

WHAT IS THE TYPE OF VENT VALVE? ..... Gate ☐ Plug Cock ☐ Other ☐

IF OTHER, SPECIFY:

ARE VENTS FULLY OPEN DURING VENTING? ..... Yes ☐ No ☐

IF NO, EXPLAIN:

DOES THE FIRM HAVE ON FILE DOCUMENTARY PROOF DEMONSTRATING THAT ADEQUATE VENTING IS ACHIEVED?

Yes ☐ No ☐

*(**SHALL** REQUIREMENT – 113.40(c)(6); HEAT DISTRIBUTION DATA AND/OR A LETTER FROM A COMPETENT PROCESS AUTHORITY DOCUMENTING THE LAST HEAT DISTRIBUTION TEST PERFORMED ON THE RETORT (DATE OF TEST, WHO PERFORMED THE TEST, THE RESULTING VENT SCHEDULE, ETC) WOULD BE ACCEPTABLE DOCUMENTATION.)*

IS A STEAM BY-PASS VALVE USED DURING VENTING? ..... Yes ☐ No ☐

IF YES, EXPLAIN:

(NOTE: VENTING PROCEDURES AND ARRANGEMENTS MUST BE THE SAME AS USED DURING THE TEMPERATURE DISTRIBUTION STUDY THAT WAS CONDUCTED ON THE RETORT TO ESTABLISH THE VENT SCHEDULE.)

IF VENTS ARE EQUIPPED WITH MUFFLERS, SPECIFY TYPE AND PERFORMANCE CHARACTERISTICS. DOES THE FIRM HAVE DOCUMENTED EVIDENCE THAT THE MUFFLER ALLOWS ADEQUATE VENTING? ..... Yes ☐ No ☐

*(**SHALL** REQUIREMENT – 113.87(G))*

WHEN THE STEAM IS TURNED ON, IS THE DRAIN OPENED FOR A TIME SUFFICIENT TO REMOVE STEAM CONDENSATE FROM THE RETORT? ..... Yes ☐ No ☐

*(**SHOULD** REQUIREMENT)*

HAS PROVISION BEEN MADE FOR CONTINUAL OR AUTOMATIC DRAINAGE OF CONDENSATE DURING RETORT OPERATION?

Yes ☐ No ☐

*(**SHALL** REQUIREMENT; A CONDENSATE TRAP OR BLEEDER LOCATED AT THE BOTTOM OF THE RETORT WOULD BE SUFFICIENT TO ASSURE CONTINUAL CONDENSATE REMOVAL.)*

DESCRIBE THE PROCEDURES USED FOR CONDENSATE REMOVAL:

IS THE RETORT EQUIPPED WITH A CONDENSATE TRAP? ..... Yes ☐ No ☐

IS THERE A CONDENSATE BLEEDER IN THE BOTTOM OF THE RETORT SHELL THAT SERVES AS AN INDICATOR OF CONTINUOUS CONDENSATE REMOVAL? ..... Yes ☐ No ☐

IF SO, IS THIS BLEEDER VISIBLE TO THE RETORT OPERATOR? ..... Yes ☐ No ☐

(SHALL REQUIREMENT)

DOES THIS CONDENSATE BLEEDER CONTINUOUSLY EMIT STEAM DURING THE THERMAL PROCESS? ..... Yes ☐ No ☐

*(**SHALL** REQUIREMENT)*

IS THE CONDENSATE BLEEDER CHECKED WITH SUFFICIENT FREQUENCY DURING RETORT OPERATION TO ASSURE ADEQUATE REMOVAL OF CONDENSATE? ..... Yes ☐ No ☐

*(**SHALL** REQUIREMENT)*

ARE THESE OBSERVATIONS RECORDED AT THE TIME THEY ARE MADE? ..... Yes ☐ No ☐

(SHALL REQUIREMENT – 113.100(a))

IF THE CONDENSATE BLEEDER IS NOT VISIBLY MONITORED, IS IT EQUIPPED WITH AN AUTOMATIC ALARM SYSTEM THAT SERVES AS A CONTINUOUS MONITOR OF CONDENSATE FUNCTIONING? ..... Yes ☐ No ☐

*(**SHALL** REQUIREMENT)*

IF AN AUTOMATIC ALARM IS USED TO MONITOR CONDENSATE FUNCTIONING, DOES IT WORK ADEQUATELY?

Yes ☐ No ☐

RETORT SPEED TIMING (113.40(c)(7))

IS THE ROTATIONAL SPEED OF THE RETORT ADJUSTED AND RECORDED WHEN THE RETORT IS STARTED, AT ANY TIME A SPEED CHANGE IS MADE, AND AT INTERVALS OF SUFFICIENT FREQUENCY TO ENSURE THAT THE RETORT SPEED IS MAINTAINED AS SPECIFIED IN THE SCHEDULED PROCESS? ..... Yes ☐ No ☐

*(**SHALL** REQUIREMENT)*

ARE THESE ADJUSTMENTS AND RECORDINGS MADE AT LEAST ONCE EVERY 4 HOURS? ..... Yes ☐ No ☐

*(**SHOULD** REQUIREMENT)*

IF NO, HOW OFTEN?

IF ROTATIONAL SPEED ADJUSTMENTS AND RECORDINGS ARE NOT MADE AT INTERVALS OF SUFFICIENT FREQUENCY, DOES THE FIRM HAVE A RECORDING TACHOMETER TO PROVIDE A CONTINUOUS RECORD OF THE RETORT SPEED?

Yes ☐ No ☐

DOES THE FIRM HAVE A MEANS OF PREVENTING UNAUTHORIZED SPEED CHANGES ON THE RETORT? ..... Yes ☐ No ☐

*(**SHALL** REQUIREMENT; A LOCK OR NOTICE FROM MANAGEMENT POSTED AT OR NEAR THE SPEED ADJUSTMENT DEVICE THAT PROVIDES A WARNING THAT ONLY AUTHORIZED PERSONS ARE PERMITTED TO MAKE ADJUSTMENTS, IS A SATISFACTORY MEANS OF PREVENTING UNAUTHORIZED CHANGES.)*

Adjustment of the reel speed changes the process time and may affect the agitation of the product. The reel speed calculated to provide the process time would be entered on the FDA 2541a (Scheduled Process Filing Form) in Part D column titled “Reel Speed” in revolutions per minute (rpm). A minimum reel speed (slower than the reel speed providing adequate-processing time) may be determined during process establishment to provide for adequate product agitation. This minimum reel speed should be entered on Form 2541a, Part D in the column titled “Other” along with an explanation of “minimum reel speed”. Minimum reel speeds for agitation may be less than the reel speed established for the process time. Reel speeds greater than the established reel speed for process time will shorten the process time. Reel speeds slower than the minimum reel speed for agitation, may not provide for adequate agitation of the product. In cases where a minimum reel speed for agitation is not identified by the processing source, determine if agitation is critical to the process. Note some processes are established without considering agitation. If agitation is critical to the process, the firm should have information that identifies the minimum rpm required to achieve adequate product agitation in the container. This reel speed may be the same as that established to provide for process time.

Reel speed and process time can be determined using the following formulas. To use these formulas, known values can be entered into the formula to determine unknown values or to check the values supplied by the firm on the process filing form. The capacity of the retort is normally stamped on the end of the cooker reel shaft. The approximate number of reel steps for the FMC system for each container size is provided in the table below. Please be aware that some reels may be altered. In some cases, the firm may process a smaller can size in a reel designed for a larger container (e.g. 300 in a 303 x 307 reel).

CONTAINER SIZE	*NUMBER OF STEPS PER TURN OF REEL*
211	56
300-303	47
303-307	42
401-404	35
603	24

DETERMINE THE REEL SPEED BY TIMING 10 REVOLUTIONS OF
THE RETORT REEL AND REPORT RESULTS (IN SECONDS): _____

CALCULATE THE ACTUAL PROCESS TIME USING THE FORMULA:

SECONDS FOR 10 REVS = (10 RVS)X(60 SECS) X (REEL STEPS) X (PROCESS TIME)/CAPACITY

ACTUAL PROCESS TIME = _____ MIN.

IS THE ACTUAL PROCESS TIME AT LEAST EQUAL TO THE MINIMUM PROCESS TIME FILED WITH FDA ..... Yes ☐ No ☐

CALCULATE THE PROCES SPEED IN CONTAINERS/MIN USING THE FORMULA:

CONTAINERS PER MINUTE = CAPACITY/PROCESS TIME (MIN)

CONTAINERS PER MINUTE = _____

CALCULATE THE REEL SPEED AS REVOLUTIONS PER MINUTE (RPM) USING THE FORUMLA:

RPM = CAPACITY/(REEL STEPS) X (PROCESS TIME)

REEL SPEED (RPM) = _____

IS THE REEL SPEED CALCULATED ABOVE AS CONTAINERS PER MINUTE AND/OR REVOLUTIONS PER MINUTE AT LEAST EQUAL TO THE MINIMUM REEL SPEED FILED WITH FDA? ..... Yes ☐ No ☐

(IF NO, THE LOT COULD BE UNDER PROCESSED AND SHOULD BE HANDLED AS A PROCESS DEVIATION.)

ALTERNATE FORMULAS WHICH CAN BE USED TO DETERMINE SECONDS FOR 10 REVOLUTIONS OF THE REEL:

(10 REV) X (60 SECS) X (#REEL STEPS)/(CPM)

(10 RVS) X (60 SEC)/RPM

EMERGENCY STOPS (113.40(c)(8)

IF EMERGENCY STOPS ARE NOT OBSERVED DURING PROCESSING OR REVIEW OF RECORDS, ANSWER THE FOLLOWING QUESTIONS BY REVIEW OF WRITTEN SOPS OR INTERVIEW WITH MANAGEMENT. INDICATE HOW THIS INFORMATION WAS OBTAINED:

Processing Observation ☐ Review of Processing Records ☐ Review of Sops ☐ Interview with Management ☐

IN THE CASE OF A JAM OR BREAK DOWN DURING PROCESSING OPERATIONS NECESSITATING COOLING THE RETORT, IS THE RETORT OPERATED IN SUCH A WAY THAT ENSURES THAT THE PRODUCT IS COMMERCIALLY STERILE?

Yes ☐ No ☐

(THIS CAN BE ACHIEVED BY REPROCESSING OR REPACKING & REPROCESSING.)

IF NO, IS THE PRODUCT DESCARDED? ..... Yes ☐ No ☐

*(**SHALL** REQUIREMENTS)*

IF OPERATED AS A STILL RETORT, ARE ALL CONTAINERS GIVEN A FULL, STILL RETORT PROCESS BEFORE THE RETORT IS COOLED? ..... Yes ☐ No ☐ N/A ☐

IF SO, IS THE STILL PROCESS SCHEDULE READILY AVAILABLE TO THE RETORT OPERATOR? ..... Yes ☐ No ☐

*(**SHALL** REQUIREMENTS)*

IF ANY CONTAINERS ARE IN THE RETORT INTAKE VALVE OR IN TRANSFER VALVES BETWEEN COOKER SHELLS AT THE TIME OF BREAKDOWN, ARE THE CONTAINERS REPROCESSED, REPACKED AND REPROCESSED, OR DISCARDED?

Yes ☐ No ☐

*(**SHALL** REQUIREMENT – (113.40(c)(8)(i))*

IS BOTH THE TIME AT WHICH THE REEL STOPPED AND THE TIME THE RETORT WAS USED FOR A STILL RETORT PROCESS MARKED ON THE RECORDING CHART AND ENTERED ON OTHER PRODUCTION RECORDS? ..... Yes ☐ No ☐ N/A ☐

*(**SHALL** REQUIREMENT – (113.40(c)(8)(ii))*

IF THE RETORT IS COOLED FOLLOWING AN EMERGENCY STOP, ARE SUBSEQUENT HANDLING METHODS USED FOR CONTAINERS IN THE RETORT AT THE TIME OF STOPPING AND COOLING ENTERED ON PRODUCTION RECORDS?

Yes ☐ No ☐ N/A ☐

*(**SHALL** REQUIREMENT – (113.40(c)(8)(ii))*

DESCRIBE ANY INCIDENCES OF EMERGENCY STOPS THAT WERE NOT HANDLED ACCORDING TO 113.40(c)(8):

TEMPERATURE DROPS (113.40(c)(9)

IF TEMPERATURE DROPS ARE NOT OBSERVED DURING THE INSPECTION OR REVIEW OF PROCESSING RECORDS, ANSWER THE FOLLOWING QUESTIONS BY REVIEW OF THE FIRM'S SOPS OR INTERVIEW WITH MANAGEMENT. INDICATE HOW THIS INFORMATION WAS OBTAINED:

Processing Observation ☐ Review of Processing Records ☐ Review of Sops ☐ Interview with Management ☐

IF THE TEMPERATURE OF THE RETORT DROPS BELOW THE TEMPERATURE SPECIFIED IN THE SCHEDULED PROCESS WHILE CONTAINERS ARE IN THE RETORT, IS THE REEL STOPPED PROMPTLY? ..... Yes ☐ No ☐

*(**SHALL** REQUIREMENT)*

IF YES, IS AN AUTOMATIC DEVICE USED TO STOP THE REEL? ..... Yes ☐ No ☐

*(**SHOULD** REQUIREMENT)*

BEFORE THE RETORT IS RESTARTED, ARE ALL CONTAINERS IN THE RETORT GIVEN A COMPLETE SCHEDULED STILL RETORT PROCESS IF THE TEMPERATURE DROP WAS 10°F OR MORE BELOW THE SPECIFIED TEMPERATURE?

Yes ☐ No ☐ N/A ☐

IF YES, ARE BOTH THE TIME AT WHICH THE REEL STOPPED AND THE TIME THE RETORT WAS USED FOR A STILL RETORT PROCESS MARKED ON THE RECORDING CHART AND OTHER PRODUCTION RECORDS? ..... Yes ☐ No ☐ N/A ☐

*(**SHALL** REQUIREMENTS)*

ALTERNATIVELY, IF THE TEMPERATURE DROP IS 10°F OR MORE, IS CONTAINER ENTRY TO THE RETORT STOPPED AND THE REEL RESTARTED TO EMPTY THE RETORT? ..... Yes ☐ No ☐ N/A ☐

IF YES, ARE THE DISCHARGED CONTAINERS EITHER:

Reprocessed ☐ Repacked & Reprocessed ☐, or Discarded ☐ ?

ARE SUBSEQUENT HANDLING METHODS USED FOR CONTAINERS IN THE RETORT AT THE TIME OF THE TEMPERATURE DROP ENTERED ON PRODUCTION RECORDS? ..... Yes ☐ No ☐ N/A ☐

*(**SHALL** REQUIREMENTS)*

IF THE TEMPERATURE DROP IS LESS THAN 10°F, IS THE PRODUCT GIVEN AN AUTHORIZED EMERGENCY STILL PROCESS BEFORE RESTARTING THE RETORT REEL? ..... Yes ☐ No ☐

IS CONTAINER ENTRY INTO THE RETORT STOPPED AND AN AUTHORIZED EMERGENCY AGITATING PROCESS USED BEFORE CONTAINER ENTRY TO THE RETORT IS RESTARTED? ..... Yes ☐ No ☐

*(**SHALL** REQUIREMENTS)*

DURING AN EMERGENCY AGITATING PROCESS, ARE CONTAINERS PREVENTED FROM ENTERING THE RETORT?

Yes ☐ No ☐ N/A ☐

WHEN EMERGENCY PROCEDURES ARE USED, ARE PROCESSES AND PROCEDURES NOTED ON PRODUCTION RECORDS?

Yes ☐ No ☐ N/A ☐

DESCRIBE ANY INCIDENCES OF TEMPERATURE DROPS THAT WERE NOT HANDLED ACCORDING TO 113.40(C)(9):